Abbott Launches Whole-Genome Sequencing Oncodetect® Molecular Residual Disease (MRD) Test To Detect Traces Of Cancer During And After Treatment

- *Powered by whole-genome sequencing and MAESTRO* technology, the next-generation Oncodetect test takes a distinct approach to MRD, tracking up to 5,000 patient-specific variants with a limit of detection below one part per million under high-end inputs* [1, 2, 3]
- *The next-generation Oncodetect test builds on more than 20 years of trusted leadership in using genomic information to personalize cancer care*
- *Modeling estimates more than 3 million U.S. patients with solid tumors could potentially benefit from MRD testing‡*

ABBOTT PARK, Ill., Oct. 26, 2026 /PRNewswire/ -- For many people with cancer, completing treatment can bring a new uncertainty: Is my cancer really gone?

Even after treatment, small amounts of cancer may remain in the body at levels that can be difficult to detect. Molecular residual disease (MRD) testing looks for traces of circulating tumor DNA (ctDNA) in the blood, providing additional information that can help physicians understand recurrence risk, monitor treatment response, and inform decisions about what comes next.[4,5]

To help address this need, Abbott (NYSE: ABT) today announced the commercial availability of its next-generation Oncodetect® MRD test, a personalized, tumor-informed, whole-genome sequencing test designed to provide molecular insights during and after cancer treatment.[1,2]

For more than 20 years, the Oncotype DX Breast Recurrence Score® test has helped physicians use genomic information to personalize breast cancer treatment and is recognized as a standard of care in early-stage breast cancer.[6] The next-generation Oncodetect test builds on that foundation, expanding Abbott's ability to provide molecular insights across the cancer care continuum. Abbott's broad cancer diagnostics portfolio spans cancer screening, hereditary cancer testing, genomic profiling, recurrence risk assessment, and MRD testing.

The personalized test uses a sample of each patient's tumor to identify its unique DNA markers, then looks for those same signals in the blood. At the heart of the next-generation Oncodetect test is MAESTRO, a technology developed at the Gerstner Center for Cancer Diagnostics at the Broad Institute of MIT and Harvard and enhanced by Abbott. Combined with whole-genome sequencing, this approach expands variant discovery from up to 200 variants in the first-generation test up to as many as 5,000 patient-specific variants.[1,5] MAESTRO technology enriches tumor DNA from blood up to 1,000-fold before sequencing, making cancer signals easier to detect.[1,2] Together, these advances achieve a 30-fold improvement in limit of detection to below one part per million.[‡,3,7,8] This ultrasensitive performance is designed to identify residual disease when ctDNA levels are especially low, including in early-stage disease and post-treatment settings.[9,10]

Importantly, MAESTRO enables cost-efficient sequencing, allowing Abbott to offer the whole-genome Oncodetect test to all new patients from day one, rather than reserving the technology for select cases.

"For many people affected by cancer, finishing treatment does not mean the uncertainty ends," said Maimah Karmo, a triple-negative breast cancer survivor and president of the Tigerlily Foundation, a national women's health and oncology patient advocacy organization. "Waiting for the next scan and wondering whether cancer may return can take an emotional toll. New tools that give care teams more information about recurrence risk can support more meaningful conversations about what comes next."

Designed to detect when disease is hardest to find

MRD tests differ in how they identify and track tumor-specific DNA. The next-generation Oncodetect test takes a distinct approach, combining broad whole-genome variant tracking with MAESTRO technology that enriches tumor DNA from blood to create many opportunities to detect ctDNA when very little is present.

- **Broad variant tracking:** Whole-genome sequencing tracks up to 5,000 patient-specific variants, expanding opportunities to detect residual disease at critical clinical decision points.[1,2]
- **Tumor DNA enrichment:** MAESTRO enriches tumor DNA detection up to ~1,000-fold [1,2]
- **Ultrasensitive detection:** A limit of detection below one part per million‡, while maintaining >99% analytical specificity.[3,7,8]

This ultrasensitive performance is designed to identify residual disease when ctDNA levels are especially low, including in early-stage cancers, low-shedding cancers such as prostate, lung, kidney, and HR+ breast, and post-treatment settings.[9-11]

Building the evidence behind next-generation MRD

Clinical studies are evaluating the performance of the next-generation Oncodetect test across multiple solid tumors. In patients with locally advanced esophageal cancer, longitudinal testing detected ctDNA before recurrence in all 14 patients who

experienced recurrence, achieving 100% sensitivity.[12] In the PARTNER triple-negative breast cancer study, the next-generation test identified 90% of patients who later experienced distant recurrence within five years from a single post-surgery blood draw, a three-fold improvement over the first-generation test.[13]

New Beta-CORRECT data presented at the European Society of Medical Oncology (ESMO) congress showed a 30% absolute improvement in sensitivity for recurrence within two years with the next-generation Oncodetect test, compared with the first-generation test, at a single post-surgical time point in patients with stage II–IV colorectal cancer.[14]

"We've spent decades getting better at treating cancer once we find it. The next chapter is about understanding what may be happening at the molecular level during and after treatment," said Dr. Rick Baehner, divisional vice president, chief medical officer, precision oncology, Abbott's cancer diagnostics business. "MRD represents an important evolution in precision oncology, helping move cancer care beyond waiting for signs of recurrence toward more informed decisions throughout a patient's care. Our next-generation Oncodetect test reflects that evolution, bringing together whole-genome sequencing and MAESTRO technology to help detect residual disease when the molecular signal is extremely low."

Advancing MRD in cancer care

Abbott's precision oncology tests are fully integrated into leading electronic health record systems, making it easier for physicians to order tests and access results within their existing clinical workflows.

Abbott continues to build clinical evidence for MRD testing through more than 20 ongoing studies evaluating the next-generation Oncodetect test across tumor types, academic collaborations, and real-world research. The company is also working to broaden patient access through payor coverage and international expansion.

Frequently asked questions

Who is MRD testing for and how does it work?
The Oncodetect test is available for patients with solid tumors and must be ordered by a healthcare provider. The personalized, tumor-informed test uses a sample of the patient's tumor, typically from a patient's biopsy or surgery, to identify DNA changes unique to their cancer to create a molecular "fingerprint." A blood sample is then collected and tested for those same tumor-specific signals, with additional blood draws over time providing a molecular view of how disease may be changing.

What is the next-generation Oncodetect test?
The next-generation Oncodetect test is a tumor-informed molecular residual disease (MRD) blood test designed to detect extremely low levels of circulating tumor DNA (ctDNA) during and after cancer treatment. Powered by whole-genome sequencing and MAESTRO technology, the test has a low limit of detection below one part per million,‡ while maintaining >99% analytical specificity. [1-3,8]

How does the next-generation Oncodetect test improve on the first-generation Oncodetect test?
The next-generation Oncodetect test moves from whole-exome to whole-genome sequencing, significantly expanding the number of tumor-specific signals it can track and improving its ability to detect extremely low levels of ctDNA. Key advancements include:

- **More opportunities to detect residual disease:** Tracks up to 5,000 patient-specific variants, compared with up to 200 with the first-generation test.[1,5]
- **Greater sensitivity:** A low limit of detection below one part per million‡, a 30-fold improvement over the first-generation test.[3,7,8]
- **Deeper detection:** MAESTRO technology enriches tumor signals up to ~1,000-fold, helping identify ctDNA when extremely low amounts are present.[1]

Why does detecting ctDNA at low levels matter?
Circulating tumor DNA (ctDNA) is genomic material shed by tumors into the bloodstream. ctDNA positivity in patients who have received treatment is strongly prognostic of cancer recurrence, even at very low levels.[13] Detecting ctDNA at low levels can help identify patients at higher risk of recurrence and provide information to support treatment and surveillance decisions.[5]

About the Oncodetect® test
The next-generation Oncodetect test is a whole-genome sequencing-based tumor-informed molecular residual disease (MRD) test designed to provide a personalized approach to detecting and monitoring residual cancer in patients with solid tumors. The test analyzes circulating tumor DNA (ctDNA) shed into the bloodstream by tumors, offering insights into changes in ctDNA levels over time. This quantitative assessment of ctDNA (measured as MTM/mL) helps healthcare providers better understand a patient's MRD status and make informed treatment decisions.

The Oncodetect® test was developed, and its performance characteristics determined by Genomic Health, Inc. Performance characteristics may not apply in tumor types not included in this test's clinical validation. The test has not been cleared or approved by the US Food and Drug Administration. The test is performed at Genomic Health Inc. The Genomic Health Inc. lab performing this test is certified under CLIA regulations and qualified to perform high-complexity clinical laboratory testing.

About Abbott

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 122,000 colleagues serve people in more than 160 countries.

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*MAESTRO = minor allele enriched sequencing through recognition oligonucleotides
MAESTRO was developed by researchers at the Broad Institute of MIT and Harvard. Abbott enhanced the technology for use in the next-generation Oncodetect test.
† Internal estimate for addressable patient populations based on solid tumors amenable to MRD testing.
‡ Under high-end inputs

1. Tsvetanova B, et al. Association for Molecular Pathology 2025 Annual Meeting Abstracts. J Mol Diagn. 2025;27 Suppl:S113.
2. Gydush G, Nguyen E, Bae JH, et al. Massively parallel enrichment of low-frequency alleles enables duplex sequencing at low depth. Nat Biomed Eng. 2022;6:257–266. doi:10.1038/s41551-022-00855-9.
3. Abbott Cancer Diagnostics. LoD and Precision Results from MRD v2 AV. Internal presentation. August 3, 2026.
4. Kotani, D., Oki, E., Nakamura, Y. et al. Molecular residual disease and efficacy of adjuvant chemotherapy in patients with colorectal cancer. Nat Med 29, 127-134 (2023). https://doi.org/10.1038/s41591-022-02115-4
5. Diergaarde B, Young G, Hall DW, et al. Circulating Tumor DNA as a Marker of Recurrence Risk in Stage III Colorectal Cancer: The α-CORRECT Study. J Surg Oncol. 2025;132(1):175-186. doi:10.1002/jso.27989
6. Exact Sciences. Oncotype DX Breast Recurrence Score® Test Surpasses 2 Million Patients Worldwide. February 3, 2026.
7. LoBello J, et al. Poster 2025. Exact Sciences Corporation; Madison, WI.
8. Abbott Cancer Diagnostics. Oncodetect v2 Analytical Specificity. Internal presentation. August 25, 2026.
9. Boukouris, A.E., Michaelidou, K., Joosse, S.A. et al. A comprehensive overview of minimal residual disease in the management of early-stage and locally advanced non-small cell lung cancer. npj Precis. Onc. 9, 178 (2025). https://doi.org/10.1038/s41698-025-00984-9
10. Hashimoto T, Nakamura Y, Oki E, et al. Bridging horizons beyond CIRCULATE-Japan: a new paradigm in molecular residual disease detection via whole genome sequencing-based circulating tumor DNA assay. Int J Clin Oncol. 2024;29(5):495-511. doi:10.1007/s10147-024-02493-4
11. Bettegowda C, Sausen M, Lear y RJ, et al. Detection of circulating tumor DNA in early- and late-stage human malignancies. Sci Transl Med. 2014;6(224):224ra24.
12. Rhoades J, Patel A, Xiong K, Blewett T, Li R, Walsh L, Crnjac A, Ratty JH, Limbo O, Hannigan A, Remland J, Brais L, Jain P, Sridhar S, Gilligan K, Carnes M, Shin KY, Catalano P, Wiener D, Papke DJ Jr, Ramesh A, Fu Y, Garces J, Mazloom A, Costa GL, Hu J, Makrigiorgos GM, Culver BP, Adalsteinsson VA, Enzinger P, Mamon H. Ultrasensitive circulating tumor DNA analysis improves detection of molecular residual disease in locally advanced esophageal cancer. Clin Cancer Res. 2026. In press.
13. Dooley A, et al. Evaluation of whole-exome and whole-genome sequencing tumor-informed circulating tumor DNA MRD assays in patients with early triple-negative breast cancer (TNBC) receiving neoadjuvant chemotherapy (NAC) with or without olaparib: A prospective sub-study of the PARTNER trial. Poster presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; May 29–June 2, 2026; Chicago, IL. J Clin Oncol. 2026;44(16_suppl):570. DOI:10.1200/JCO.2026.44.16_suppl.570.
14. Hashimoto, T. et al. Validation of the ultrasensitive tumor-informed WGS MAESTRO MRD assay in β-CORRECT. Poster 4426P presented at ESMO 2026; October 23-27, 2026; Madrid, Spain.

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